



07 April 2019

Electronic Delivery Via CDX

U.S. Environmental Protection Agency
Office of Pollution Prevention & Toxics
New Chemicals Program
EPA East Building, Room 4133
1201 Constitution Avenue, NW
Washington, DC 2,0004-3302

Re: TSCA Experimental Release Application of Synthetic Genomics, Inc.
Open Pond Research and Development: The green microalgal strain *Parachlorella*
STR26155 engineered with green fluorescent protein (GFP) for environmental tracking

Ladies and Gentlemen:

On behalf of Synthetic Genomics, Inc., I enclose its application for authorization to conduct the outdoor, open pond R&D activities described herein with the green microalgal strain *Parachlorella* STR26155 engineered with green fluorescent protein (GFP) for environmental tracking.

This submission represents the culmination of 18 months of investigation and data collection, in consultation with EPA, to lay the foundation for efficient review of future TERAs for future outdoor, open pond algae research and development work. Extensive and flexible outdoor testing is a critical and necessary stage of development for commercial algae cultivation intended to be conducted outdoors in the future on a large scale.

The aim of this TERA and the research for which it seeks authorization in part is to establish baseline environmental conditions in and around the test facility, and to evaluate and confirm the sufficiency of control and monitoring equipment and techniques developed for this and other similar outdoor R&D programs. To facilitate this work and appropriate public consultation, we have minimized confidential business information (CBI) claims to the greatest extent possible.

We expect that these efforts, in collaboration with EPA, will establish a more predictable framework for future EPA reviews of outdoor algae R&D activities at our test facility, presumptively sufficient to permit the Agency to make a reasoned evaluation of the health and environmental effects of the microorganism under the conditions of use. Future TERAs built on the framework would allow EPA to streamline and focus its future reviews more narrowly on the relevant properties of the organism rather than the sufficiency of baseline information or control and monitoring techniques. With greater experience, EPA will need to develop a practicable decision framework for the research program TERAs

anticipated by the regulation, balancing innovators' need for nimble flexibility during R&D with a reasonable and appropriate level of environmental protection consistent with TSCA. We hope you will review this TERA with these larger goals in mind.

We look forward to working with you.

Very truly yours,

DocuSigned by:

David Hanselman



Signer Name: David Hanselman
Signing Reason: I am the author of this document
Signing Time: 4/7/2019 7:23:01 PM PDT

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